## **REMARKS**

In the Office Action dated August 8, 2006, the Examiner states that this application contains the following groups of inventions that are not so linked as to form a single general inventive concept under PCT Rule 13.1.

- I. Claims 1-7, drawn to conotoxin peptides and derivatives.
- II. Claims 9, 11-12 and 14, drawn to methods of treating urinary conditions/diseases.
- III. Claims 9, 11-12 and 14, drawn to methods of treating cardiovascular conditions/diseases.
- IV. Claims 9, 11-12 and 14, drawn to methods of treating mood disorders.
- V. Claims 9-12 and 14, drawn to methods of treating neuropathic pain.
- VI. Claims 9, 11-12 and 14, drawn to methods of treating migraine.
- VII. Claims 9, 11-12 and 14, drawn to methods of treating inflammation.
- VIII. Claims 1 and 13, drawn to a method of using conotoxin peptides in the manufacture of a medicament.

In the first instance, Applicants have amended claims 8-10, 11 and 13. Specifically, claim 11 is amended to depend from any one of claims 1-5. Claims 8-10 and 13 have been properly reworded as method claims. No new matter has been introduced by the amendment to claims 8-10, 11 and 13.

In order to be fully responsive to the Examiner's requirements for restriction,

Applicants provisionally elect, with traverse, to prosecute the subject matter of Group I, Claims

1-7, drawn to conotoxin peptides and derivatives. However, pursuant to 37 C.F.R. §§1.111 and

1.143, Applicants hereby traverse the Examiner's requirement for restriction and request reconsideration thereof in view of the following remarks.

A requirement for restriction presupposes an analysis of the subject application in light of the rules governing this practice, i.e., 37 C.F.R. §1.499 and PCT Rules 13.1 and 13.2. PCT Rule 13.1, first sentence, states: "The international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ('requirement of unity of invention')." (Emphasis added.) PCT Rule 13.2 states: "The expression "technical features' shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art." (Emphasis added.)

The Examiner alleges that the present inventions listed as Groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features. Specifically, the Examiner alleges that the technical feature of the groups, which is conotoxin peptides, is not a contribution over the prior art. In this regard, the Examiner relies on certain prior art. The Examiner states that Lewis (WO 0020444 A1) teaches a conotoxin peptide with the sequence NGVCCGYKLCH(Hyp)C, which contains four cysteine residues which participate in two disulphide bonds that give the peptides of this class the functional conformation they have in common. The Examiner alleges that Balaji et al. (*J. Biol. Chem.* 275(50): 39516-22, 2000) teach conotoxins with 1, 2, 7, 10 cysteine placement in the peptide sequence, which determines the conformation of the native peptide and therefore its binding characteristics. The Examiner appears to be of the opinion that the present invention lacks inventive step in view of prior art. Therefore, the Examiner reasons that claims 1-14 do not include a special technical feature, and cannot share a special technical feature.

Applicants respectfully submit that unity of invention is the issue at hand. The Examiner should not rely on the evaluation of inventive step in order to determine whether the requirement of unity of invention is satisfied under PCT Rule 13.1. Applicants should be given the opportunity to argue the merits of the case during prosecution. Restriction of the claims on this basis would deny Applicants such an opportunity.

In addition, the Examiner alleges that the peptides of claims 1-7 do not necessarily share a common core structure. The Examiner alleges that the peptides of claims 1-7 would not function in the context of the present claims.

In this regard, Applicants respectfully submit that the peptides of claims 1-7 belong to a novel  $\chi$ -conotoxin family that is recognized by the present invention. Notably, claims 2-7 are all dependent from claim 1.

Moreover, Applicants respectfully submit that the present invention recognizes certain novel  $\chi$ -conotoxin peptides that are useful as inhibitors of neuronal noradrenaline transporters of neurotransmitters. This unique recognition provides the basis for developing therapeutic products and protocols for treatment or prophylaxis of diseases and conditions in a mammal in which the inhibition of neuronal noradrenaline transporter is associated with effective treatment or prophylaxis. Applicants submit that the methods of claims 8-14, as amended, employ  $\chi$ -conotoxin peptides of the present invention and are clearly intended to achieve the treatment or prophylaxis of diseases and conditions in which the inhibition of neuronal noradrenaline transporter is associated with effective treatment or prophylaxis. Thus, Applicants respectfully submit that all claims presented in the present application share the same technical feature. Applicants submit that the present claims, when considered as a whole, define a contribution over the prior art, and should be examined in the same application.

Furthermore, Applicants submit that, as acknowledged by the Examiner, where product claims are elected, the withdrawn process claims that depend from the elected allowable product claims will be rejoined. The process claims that depend from the patentable product claims will be entered as a matter of right if the amendment is presented prior to final rejection or allowance. In this connection, Applicants submit that even assuming that the restriction requirement is maintained, in the event claims 1-7 are allowed, claims 8-14 should be rejoined in

Finally, Applicants respectfully submit that a determination to make the pending restriction requirement final must evidence the patentable distinctness of all eight defined groups, one from the other, as presented by the Examiner.

Accordingly, it is respectfully submitted that claims 1-14 satisfy the requirements for unity of invention. Applicants respectfully urge that the Examiner reconsider and withdraw the requirement for restriction and provide an action on the merits with respect to all the claims.

Respectfully submitted,

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view of the amendment to claims 8-14.

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